UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MEDICAL MUTUAL OF OHIO, on behalf of itself and all others similarly situated, **Plaintiff,** **v.** **REGENERON PHARMACEUTICALS, INC.,** **Defendant.**	**Case No. _____** **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

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Plaintiff Medical Mutual of Ohio alleges the following against Defendant Regeneron Pharmaceuticals, Inc.

I. PARTIES

1. Plaintiff Medical Mutual of Ohio ("Plaintiff" or "MMO") is a not-for-profit mutual insurance company organized under Ohio law with its principal place of business located at 2060 E. 9th Street, Cleveland, OH, 44115. MMO brings these claims of itself, its subsidiaries, and those similarly situated.

2. MMO is the oldest health care plan in Ohio. MMO provides individual and group health benefits, Medicare supplemental insurance, and other ancillary products, such as vision, dental, and prescription drug coverage.

3. MMO provides, among other things, (a) Medicare benefits through contracts with the Centers for Medicare and Medicaid Services ("CMS") for Medicare beneficiaries through various Medicare Advantage plans offered under Medicare Part C, and prescription drug benefits under Medicare Part D; and (b) private commercial health plan benefits that cover medical expenses and prescription drug costs incurred by plan beneficiaries on an individual or group basis. MMO, either directly or through its health plan subsidiaries, insures and administers health plan benefits for its members.

4. Regeneron Pharmaceuticals, Inc. ("Regeneron") is a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Regeneron is a publicly traded pharmaceutical company with a market capitalization of more than $66 billion (as of December 17, 2021).

II. SUMMARY

5. Regeneron manufactures and sells Eylea (aflibercept), a prescription drug administered by injection for the treatment of wet age-related macular degeneration ("wet AMD"),

an eye disease that can render patients legally blind. From 2012 to at least June 2020, Eylea's wholesale list price was $1,850 per treatment.

6. Although a competing and equally effective drug, Avastin, cost only about $55 per treatment during the same period, Eylea's sales have far exceeded the sales of Avastin or any other alternative drug. Regeneron has reaped billions of dollars in annual revenue from Eylea's sales.

7. Since 2012, Regeneron has built Eylea's market dominance and maintained its exorbitant price through an illegal scheme that directly injured MMO and other healthcare plans. On a regular basis, Regeneron transferred funds to a so-called "charity," the Chronic Disease Fund, Inc. ("CDF"), to provide financial assistance to patients for their out-of-pocket share of Eylea's costs. Pursuant to a secret arrangement between Regeneron and CDF, the funds provided by Regeneron were calculated to cover patients' out-of-pocket costs for Eylea but not for competing drugs. Regeneron's arrangement with CDF made Eylea cheaper for patients—but not for the Medicare program or for private healthcare plans—in comparison with alternative drugs.

8. As a result, Regeneron gained an unfair advantage over its competitors by distorting the cost of Eylea in the view of patients and their prescribers, while increasing the costs borne by Medicare and private healthcare plans. The payments funneled by Regeneron through CDF operated as kickbacks to patients who otherwise had a contractual incentive to choose an equally effective but lower-cost drug. Regeneron's scheme thus violated the federal Anti-Kickback statute, among other laws.

9. Regeneron concealed its illegal scheme from the public, including MMO and other healthcare plans, until the scheme was exposed by an action against Regeneron filed by the U.S. Department of Justice in June 2020 (the "DOJ Action"). *United States v. Regeneron Pharms, Inc*., No. 20-CV-11217-FDS (D. Mass.).

10. As described in further detail below, evidence revealed by the DOJ Action

demonstrates not only Regeneron's extensive coordination with CDF, but also Regeneron executives' awareness that this coordination violated federal law, and that wet AMD patients and prescribers opted for Avastin in the absence of Regeneron's kickback funding.

11. To date, MMO has paid more than $39.9 million to cover patients' costs with respect to Eylea. Regeneron's illegal scheme targeted claims for Eylea paid by MMO and other healthcare plans.

12. Because MMO was directly injured by Regeneron's scheme, MMO brings this action under the federal Racketeer Influenced and Corrupt Organizations ("RICO") Act and state laws governing fraudulent concealment, tortious interference with contractual relationships, unjust enrichment, and unfair and deceptive trade practices.

III. BACKGROUND

13. The U.S. Food and Drug Administration approved Eylea as a treatment of neovascular (wet) age-related macular degeneration ("wet AMD") in 2011. Soon thereafter, Regeneron developed a covert pricing strategy for Eylea: by paying patients' out-of-pocket costs through a supposedly independent "charity," Regeneron could neutralize the incentive systems used by Medicare and private healthcare plans to guide covered patients to lower-cost but equally effective drugs.

14. By reducing or even eliminating patients' and prescribers' cost-sensitivity, Regeneron's scheme increased market demand for Eylea over less expensive alternative drugs, maintained Eylea's exorbitant price, and shifted a higher percentage of Eylea's net cost to healthcare plans, including MMO. Pursuant to this scheme, Regeneron gained far more in sales revenue than it paid to the supposed "charity."

15. Regeneron implemented its scheme in close coordination with CDF. On a regular basis, Regeneron and CDF discussed the amount of funds needed to cover the anticipated cost-

sharing obligations of patients using Eylea. Regeneron then transferred the necessary funds to CDF with the understanding and agreement that the funds would be used solely for the benefit of Eylea patients, as opposed to patients using alternative drugs.

16. Regeneron's scheme rendered Eylea cost-free in the view of patients and their prescribing physicians, while healthcare plans paid Eylea's entire net cost. In effect, Regeneron's scheme covertly funneled illegal kickbacks to patients through CDF, giving patients and their prescribers a powerful financial incentive to choose Eylea over alternative drugs. When choosing among alternative drugs, patients naturally prefer drugs that are cheaper or even cost-free. Similarly, prescribers naturally favor alternative drugs that their patients can more easily afford.

17. Regeneron widely advertised to patients and physicians the availability of CDF's financial assistance for Eylea's out-of-pocket costs. Regeneron did so through a program called "EYLEA4U," which Regeneron implemented in concert with CDF and The Lash Group LLC (the "Lash Group"), a pharmaceutical industry consulting firm. The EYLEA4U program connected patients and prescribers with CDF, assisted them in submitting claims to healthcare plans such as MMO, and facilitated the plans' payment of claims tainted by Regeneron's illegal kickbacks.

18. Regeneron, CDF, and the Lash Group never disclosed to MMO and other healthcare plans, or to the public at large, the illegal aspects of Regeneron's relationship with CDF. In particular, they concealed the fact that Regeneron's funding of CDF was designed to cover anticipated demand by Eylea patients exclusively. Moreover, as recently disclosed in the DOJ Action, Regeneron executives concealed from the company's own auditors the nature of Regeneron's relationship with CDF.

19. Regeneron's scheme was remarkably successful. Despite its exorbitant cost, Eylea quickly became the best-selling treatment for wet AMD in the United States, far outstripping any competing product. In 2020 alone, Eylea generated almost $5 billion in sales revenue for

Regeneron.[1] Eylea is by far Regeneron's best-selling product.

20. Medicare programs have spent over $14 billion to cover the cost of Eylea from 2013 through 2019. CMS Drug Spending, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs. Medicare Part B spent more for Eylea than any other drug in 2019. Medicare Part B Drug Spending Dashboard, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB. CMS, the agency that administers Medicare, recently singled out Eylea as illustrating the nation's drug-pricing problems, stating: "[T]he top-selling Medicare Part B drug—a common eye drug (Eylea) —was approximately two times as expensive in Medicare Part B as in comparison countries." The government thus cited Eylea as a prime example of the need to reform a dysfunctional and "anti-competitive" system that "leaves taxpayers and American seniors on the hook for paying the highest drug costs in the world." Centers for Medicare & Medicaid Services, FACT SHEET: Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period (Nov. 20, 2020), https://www.cms.gov/newsroom/fact-sheets/fact-sheet-most-favored-nation-model-medicare-part-b-drugs-and-biologicals-interim-final-rule#_ftn5.

21. MMO pays for Eylea both as a Medicare Part C (or Medicare Advantage) Plan sponsor and as a provider of private commercial health plans and as an administrator for self-insured plans.

22. MMO has paid more than $39.9 million to date to cover the cost of Eylea for its members and its self-insured group customers. As alleged below, Regeneron's scheme violated the federal RICO statute and state laws. Regeneron's scheme defrauded MMO, tortiously interfered

[1] In addition, Eylea is sold by Bayer outside the U.S. and generated approximately $3 billion in foreign 2020 sales.

with the contractual relationships between MMO and its members, and unjustly enriched Regeneron at the direct expense of MMO.

23. Under the relevant contracts, MMO plan members were obligated to bear some of the cost of their prescription drugs through co-payments, co-insurance, or deductibles. By funneling kickbacks to patients to cover the cost of their choosing Eylea over other drugs, Regeneron caused MMO to pay for Eylea even though the patients had not met their contractual cost-sharing obligations. In doing so, Regeneron improperly eliminated members' contractual incentive to use lower-cost alternatives.

24. Had this contractual incentive been undisturbed by Regeneron and its co-conspirators, MMO's members in need of wet AMD treatment would have opted for the far cheaper Avastin. Each MMO payment for Eylea was therefore tainted by Regeneron's unlawful kickback scheme.

25. The contractual provisions that create this incentive are an essential element of MMO's plans. The provisions encourage patients and prescribers to make cost comparisons when choosing among alternative drugs. The provisions thus promote price competition in the prescription drug market.

26. By nullifying the cost-comparison incentive for its own private benefit, Regeneron's scheme suppressed price competition, harmed private healthcare plans and the Medicare program, and diverted billions of dollars from the nation's taxpayers. According to one study, if patients used Avastin, at a fraction of Eylea's cost, Medicare and U.S. taxpayers would save $18 billion over ten years. *See* D. Hutton, P. Newman-Casey, M. Tavag, D. Zacks, & J. Stein, *Switching to Less Expensive Blindness Drug Could Save Medicare Part B $18 Billion Over a Ten-Year Period*, Health Affairs Vol. 33, No. 6 (2014), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2013.0832.

IV. JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1367. MMO asserts claims under the federal RICO Act, and MMO's state law claims are so related to those federal claims that they form part of the same case or controversy.

28. In addition, this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between MMO and Regeneron, and the amount in controversy exceeds $75,000.

29. This Court has personal jurisdiction over Regeneron. At all relevant times, Regeneron transacted business in Massachusetts; marketed and sold Eylea in Massachusetts to customers located in Massachusetts; and made payments to cover the cost-sharing obligations of Eylea patients located in Massachusetts.

30. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events giving rise to the claims in this action have occurred in this District. Regeneron paid for the cost-sharing obligations of a substantial number of patients located in Massachusetts.

V. FACTS

A. "Wet" Age-Related Macular Degeneration

31. Eylea is prescribed to treat neovascular or "wet" age-related macular degeneration ("wet AMD"), a major cause of progressive vision loss, especially in patients older than 50.

32. Wet AMD is commonly treated by "anti-VEGF" drug injections that can slow down, but cannot cure, the condition. VEGF, or vascular endothelial growth factor, is a protein that promotes the growth of new blood vessels. When produced in the eye, VEGF interferes with vision by stimulating the abnormal growth of blood vessels beneath the retina. Anti-VEGF drugs inhibit this growth through a continuing course of regular injections.

B. Eylea and Competing Drugs

33. Eylea is one of several anti-VEGF drugs on the market. Although it is not superior to other drugs, it is extremely expensive. At relevant times, Eylea's wholesale acquisition cost was set at $1,850 per dose. The typical recommended use of Eylea requires an injection every four weeks for the first set of doses, followed by further injections every eight weeks thereafter. Accordingly, Eylea had a cost of approximately $15,000 during the first year of treatment and more than $11,000 every year thereafter.

34. Eylea's primary competitors are Lucentis and Avastin, both manufactured by Genentech, Inc. Lucentis has been approved by the FDA to treat wet AMD and is priced comparably to Eylea at approximately $2,000 per dose. Although Genentech's other drug, Avastin, is chemically similar to Lucentis, its FDA approval is currently limited to treating certain types of cancer. Nevertheless, clinical studies show that its effectiveness in treating wet AMD is similar to that of both Eylea and Lucentis. *See* National Eye Institute, Avastin as Effective as Eylea for Treating Central Retinal Vein Occlusion (May 9, 2017), https://www.nei.nih.gov/about/news-and-events/news/avastin-effective-eylea-treating-central-retinal-vein-occlusion.

35. Avastin is widely available and commonly used for off-label use as a treatment for wet AMD at about $55 per dose, or approximately 3% of Eylea's cost.

36. Doctors have shown a willingness to choose Avastin over Eylea when financial incentives become a significant consideration. For example, a Regeneron executive testified in December 2020 that a decrease in the Medicare reimbursement rate for Eylea gave doctors a strong incentive "to switch patients from EYLEA to off-label Avastin." He also testified that "at least some patients who were switched from EYLEA to off-label Avastin (or other drugs) would be unlikely to return to EYLEA." *Regeneron Pharms., Inc. v. U.S. Dep't of Health & Human Servs*., No. 7:20-cv-10488-KMK, ECF No. 13 ¶¶ 24, 26 (S.D.N.Y. Dec. 11, 2020).

C. Medicare's Cost-Sharing Provisions

37. The federal government administers Medicare Parts A and B directly through CMS. Part A covers in-patient hospital and skilled nursing services as well as certain types of home-based care. Part B covers other medical services, including physician, diagnostic, and out-patient hospital services. Both Parts A and B include related drug coverage in certain circumstances.

38. Medicare patients may also be eligible to enroll in Medicare Part C, known as "Medicare Advantage." Medicare Advantage plans combine the benefits of Parts A and B and often include additional prescription drug coverage. Private healthcare plans provide Medicare Advantage benefits under contracts with CMS.

39. Medicare Part D subsidizes the cost of prescription drugs for eligible Medicare beneficiaries. Under this program, private healthcare plans, known as "Part D sponsors," enter into contracts with CMS to deliver prescription drug benefits to Medicare beneficiaries in exchange for a fixed per-patient fee.

40. MMO provides Medicare Advantage plans as combined packages that include Part C. The entities involved may be a health maintenance organization (HMO) or a preferred provider organization (PPO), both of which provide incentives that encourage patients to make financially prudent and efficient medical choices.

41. Under Medicare Advantage contracts, the government pays the private healthcare plan a specified monthly amount per patient. The healthcare plan is responsible for managing those funds to ensure their efficient use.

42. Medicare patients generally must pay some out-of-pocket costs. Under Medicare Advantage plans, a patient's cost-sharing obligations may take the form of premiums, deductibles, co-payments, or co-insurance. Medicare Advantage plans vary with respect to how these provisions are combined and structured, but in all cases provide a cap on the patient's annual out-of-pocket

costs, whereas other Medicare programs do not provide a cap.

43. Medicare Advantage plans cover Eylea and similar drugs, which are administered by a physician at the physician's office.

44. Claims payable by Medicare must comply with federal law, including the Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b). Healthcare providers must expressly certify such compliance. Providers use a standard form, CMS 1500, to submit claims to MMO and other payers. The form requires providers to certify that each claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute . . . ." CMS-1500, https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1500.

45. MMO's Medicare Advantage plans, like its private commercial plans, generally include cost provisions, which require that the patient pay a percentage of the cost of drugs such as Eylea, subject to an annual cap. Such cost-sharing provisions are a crucial factor in managing healthcare costs. When patients continue to bear some responsibility for out-of-pocket costs, they and their prescribers have an incentive to consider alternatives to more expensive drugs. When patients and their prescribers lack any stake in the cost of drugs, pharmaceutical manufacturers are free to raise the price of their drugs without constraint from consumers. This fundamentally distorts the market and eliminates price competition among manufacturers.

D. "Patient Assistance Programs" and the Anti-Kickback Statute

46. Drug companies have sought to neutralize cost-sharing provisions, and thereby increase their sales revenue, by paying patients' out-of-pocket costs. Federal law prohibits such attempts under the circumstances presented here.

47. The federal Anti-Kickback statute prohibits "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly

or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program," including Medicare. 42 U.S.C. § 1320a-7b(b)(2).

48. In addition, the statute prohibits (1) "knowingly and willfully mak[ing] or caus[ing] to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program," or (2) "knowingly and willfully mak[ing] or caus[ing] to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment." 42 U.S.C. § 1320a–7b(a)(1) and (2).

49. In 2005, the U.S. Department of Health and Human Services, Office of Inspector General ("OIG") issued a "Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D." The Bulletin addressed patient assistance programs ("PAPs") that help patients pay their out-of-pocket healthcare costs. The Bulletin warned that PAPs funded by drug companies "present heightened risks under the anti-kickback statute." 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005).

50. The Bulletin noted that "cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions." *Id*. But it went on to point out that drug companies may improperly use charities in ways that violate the Anti-Kickback statute and achieve anti-competitive effects:

> Subsidies provided by traditional pharmaceutical manufacturer PAPs have the practical effect of locking beneficiaries into the manufacturer's product, even if there are other equally effective, less costly alternatives (and even if the patient's physician would otherwise prescribe one of these alternatives). Subsidizing Medicare Part D cost-sharing amounts will have this same steering effect. Moreover, as we have previously noted in the Part B context, cost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the

> manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions. We are concerned that pharmaceutical manufacturers may seek improperly to maximize these profits by creating sham "independent" charities to operate PAPs; ***by colluding with independent charity programs to ensure that the manufacturer's contributions only or primarily benefit patients using its products*** (discussed in more detail below); or by manipulating financial need or other eligibility criteria to maximize the number of beneficiaries qualifying for cost-sharing subsidies.

Id. at 70,626 (emphasis added).

51. The Bulletin also stated:

> [A] core question is whether the anti-kickback statute would be implicated if a manufacturer of a drug covered under Part D were to subsidize cost-sharing amounts (directly or indirectly through a PAP) incurred by Part D beneficiaries for the manufacturer's product. Consistent with our prior guidance addressing manufacturer cost-sharing subsidies in the context of Part B drugs, we believe such subsidies for Part D drugs would implicate the anti-kickback statute and pose a substantial risk of program and patient fraud and abuse. ***Simply put, the subsidies would be squarely prohibited by the statute, because the manufacturer would be giving something of value (i.e., the subsidy) to beneficiaries to use its product. Where a manufacturer PAP offers subsidies tied to the use of the manufacturer's products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries[']*** ***incentives to locate and use less expensive, equally effective drugs***.

Id. at 70,625 (emphasis added, footnotes omitted).

52. The Bulletin also expressed concern about "the use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices." *Id*. at 70,626.

53. Finally, the Bulletin stated that a drug company's funding of "an independent, *bona fide* charity that provides cost-sharing subsidies" would likely comply with federal law if the following criteria were met:

> (a) neither the drug company itself nor any affiliate "exerts any direct or indirect influence or control over the charity or the subsidy program";

> (b) the "charity awards assistance in a truly independent manner that severs any link" between the drug company's funding and the beneficiary ("i.e., the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer");
>
> (c) the "charity awards assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan";
>
> (d) the "charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner"; and
>
> (e) the "pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products."

Id. (footnotes omitted).

54. The Bulletin concluded: "Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." *Id*. at 70,627 (footnote omitted).

55. In 2014, OIG issued a "Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs," which reiterated concerns stated in its 2005 Bulletin. 79 Fed. Reg. 31,121 (May 30, 2014). In particular, the Supplemental Bulletin pointed to the following conditions as a "critical safeguard":

> [The charity] will provide donors only with reports including data such as the aggregate number of applicants for assistance, the aggregate number of patients qualifying for assistance, and the aggregate amount disbursed from the fund during that reporting period. ***Thus, the charity would not give a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP***.

Id. at 31,123 (emphasis added).

E. Regeneron's Violations of the Anti-Kickback Statute

56. Beginning in 2013, Regeneron covertly funneled illegal kickbacks to patients

through CDF. Regeneron did so through concerted action with CDF and the Lash Group, which jointly operated and participated in the EYLEA4U program.

57. Among other things, the EYLEA4U program connected Eylea patients with CDF and facilitated payments for Eylea by healthcare plans like MMO. The program enabled Regeneron to neutralize the cost-sharing provisions in MMO's and other plans' contracts, thereby inflating demand for Eylea in competition with less-expensive alternative drugs and enabling Regeneron to maintain Eylea's exorbitant price.

58. As a result, healthcare plans like MMO were forced to pay for a higher volume of Eylea prescriptions, at higher prices, than they would have paid for in the absence of Regeneron's illegal conduct. To date, MMO has paid more than $100 million to cover patients' costs with respect to Eylea. Regeneron's illegal scheme targeted claims for Eylea paid by MMO and other healthcare plans.

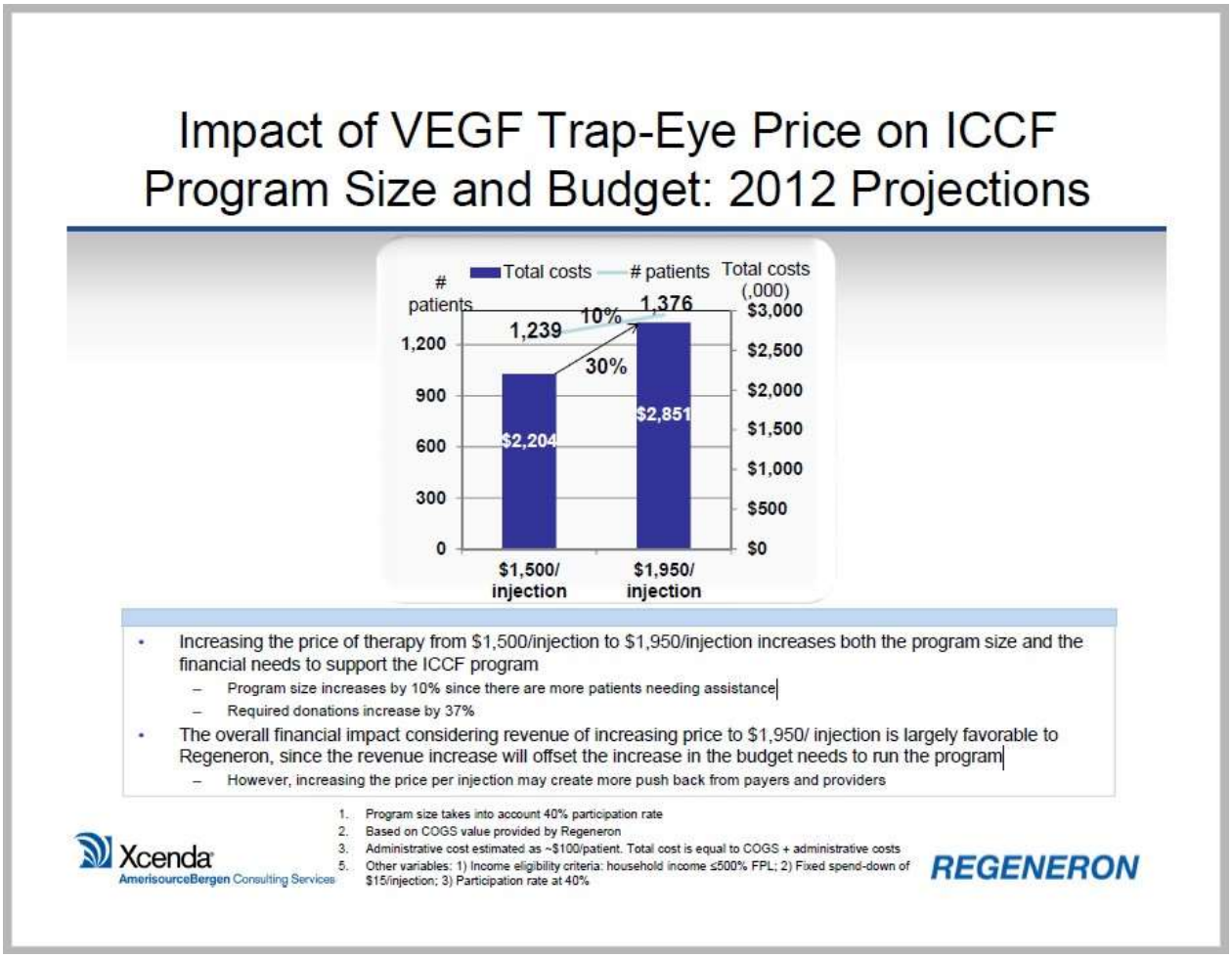
59. In 2020, Regeneron's scheme was disclosed for the first time in documents and testimony made public by the DOJ Action against Regeneron now pending in this Court. The DOJ Action disclosed the following:

60. In 2011, in anticipation of the FDA's approval of Eylea, Regeneron retained Xcenda, LLC ("Xcenda"), a consulting subsidiary of AmerisourceBergen Corp., to advise Regeneron regarding how Eylea should be marketed. Among other things, Xcenda advised Regeneron that use of a PAP could help Regeneron increase its profits by inflating Eylea's market demand and price.

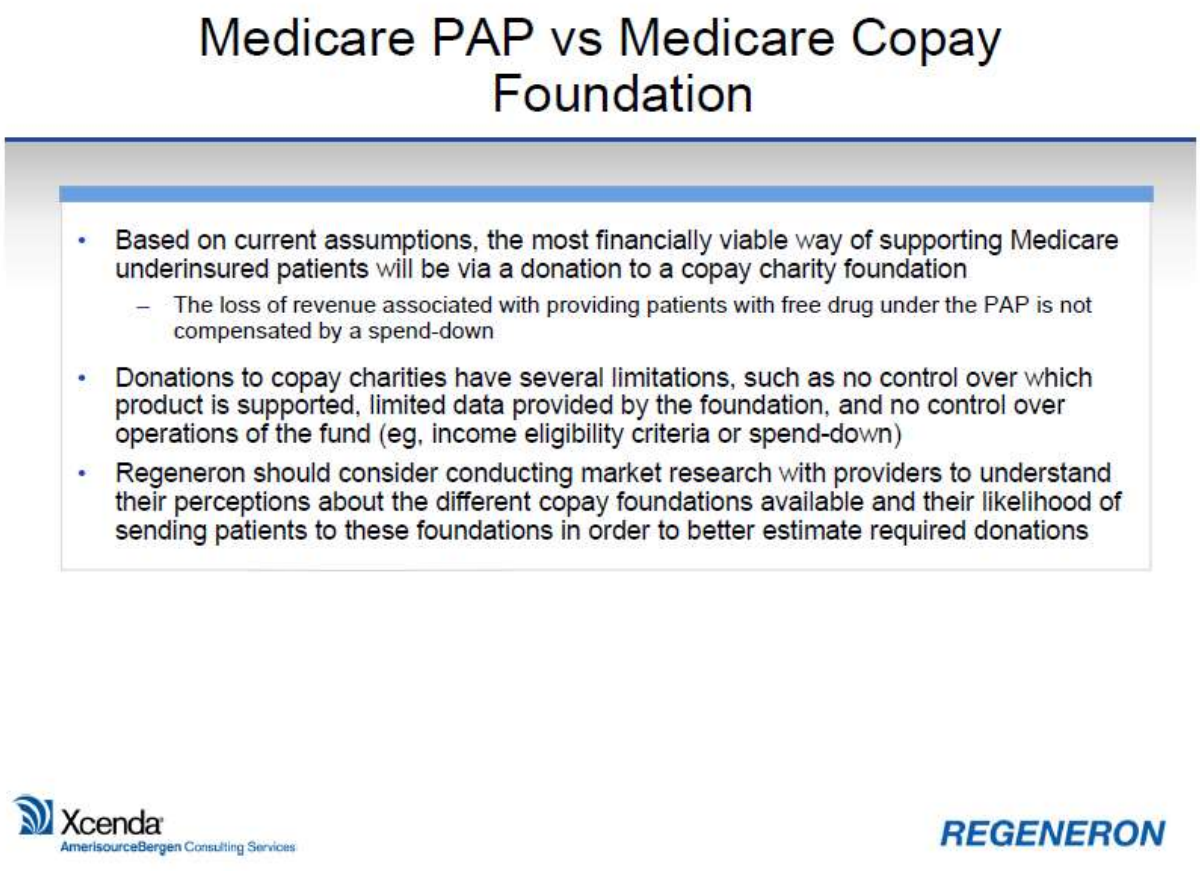
61. At the time, Regeneron was considering setting Eylea's price at $1,500 per dose. In a presentation dated May 12, 2011 (Ex. 1), Xcenda projected that use of a PAP could enable Regeneron to increase Eylea's price by as much as 30%, to $1,950 per dose.

62. Assuming a price increase to $1,950 per dose, Xcenda projected that Regeneron would need to pay roughly $3 million in 2012 to cover Medicare patients' cost-sharing obligations

but would achieve significantly more than that amount in increased sales revenue. Xcenda's analysis is shown in the following slide (*id*. at 42):



63. Xcenda made clear that federal law barred manufacturers from coordinating with PAPs in certain ways. At the same time, however, Xcenda noted that compliance with the law posed a financial disadvantage: the manufacturer would face "[u]nknown allocation of funds among products in the same therapeutic space," and thus the manufacturer might inadvertently subsidize competing drugs. *Id*. at 31. Xcenda explained in the following slide (*id*. at 58): "Donations to copay charities have several limitations, such as no control over which product is supported, limited data provided by the foundation, and no control over operations of the fund (e.g., income eligibility criteria or spend-down)."



64. Xcenda also pointed out that permissible forms of patient assistance, such as "providing free [Eylea]" to needy patients, was not "the most financially viable" option and would be financially disadvantageous to Regeneron. *Id*.

65. After receiving Xcenda's analysis and recommendations, Regeneron decided to price Eylea at $1,850, almost 25% above its initially considered price. Regeneron also decided to coordinate with a PAP in ways that violated federal law. It chose to coordinate with CDF, one of the PAPs recommended by Xcenda. First Am. Compl., *United States v. Regeneron Pharms, Inc*., No. 20-cv-11217-FDS (D. Mass.), ECF No. 65, ¶ 37 ("DOJ FAC").

66. CDF worked with several drug manufacturers to subsidize treatments for various health conditions. In a typical transaction, a prescribing physician would submit a claim to CDF to

cover a patient's cost-sharing obligation for a particular drug. CDF would pay the claim by drawing on funds that the drug's manufacturer had provided to CDF in the form of grants earmarked for the treatment of the relevant health condition. As discussed above, however, federal law barred manufacturers from coordinating with PAPs in ways that would funnel payments to subsidize the manufacturer's drugs exclusively, as opposed to competing drugs prescribed for the same health condition.

67. In choosing to coordinate with CDF, Regeneron sought to address the threat posed by Avastin, a competing and far less expensive drug. Regeneron's Senior Director for Reimbursement at the time, Cynthia Sherman, has testified that Regeneron understood that without cost-sharing assistance, patients "would end up on Avastin" instead of Eylea (or a similarly expensive drug, such as Lucentis). DOJ FAC ¶ 39.

68. As a result of Regeneron's funneling of payments through CDF, patients and their prescribing physicians would view Eylea as cheaper than Avastin—and in fact view Eylea as cost-free—even though Eylea was more than 33 times more expensive than Avastin.

69. Regeneron made its first payment to CDF in 2012. Although Xcenda had recommended an initial payment of $3 million, Regeneron reduced its payment to $600,000. Cynthia Sherman, Regeneron's executive, testified that Regeneron limited its initial payment because it "did not want to pay for Lucentis's co-pay." *Id.* ¶ 41.

70. Subsequently, Regeneron increased its payments to CDF with the understanding that Regeneron's funds would be used exclusively to pay patients' cost-sharing obligations for Eylea, as opposed to other drugs. As discussed above, this arrangement violated the law and defrauded MMO.

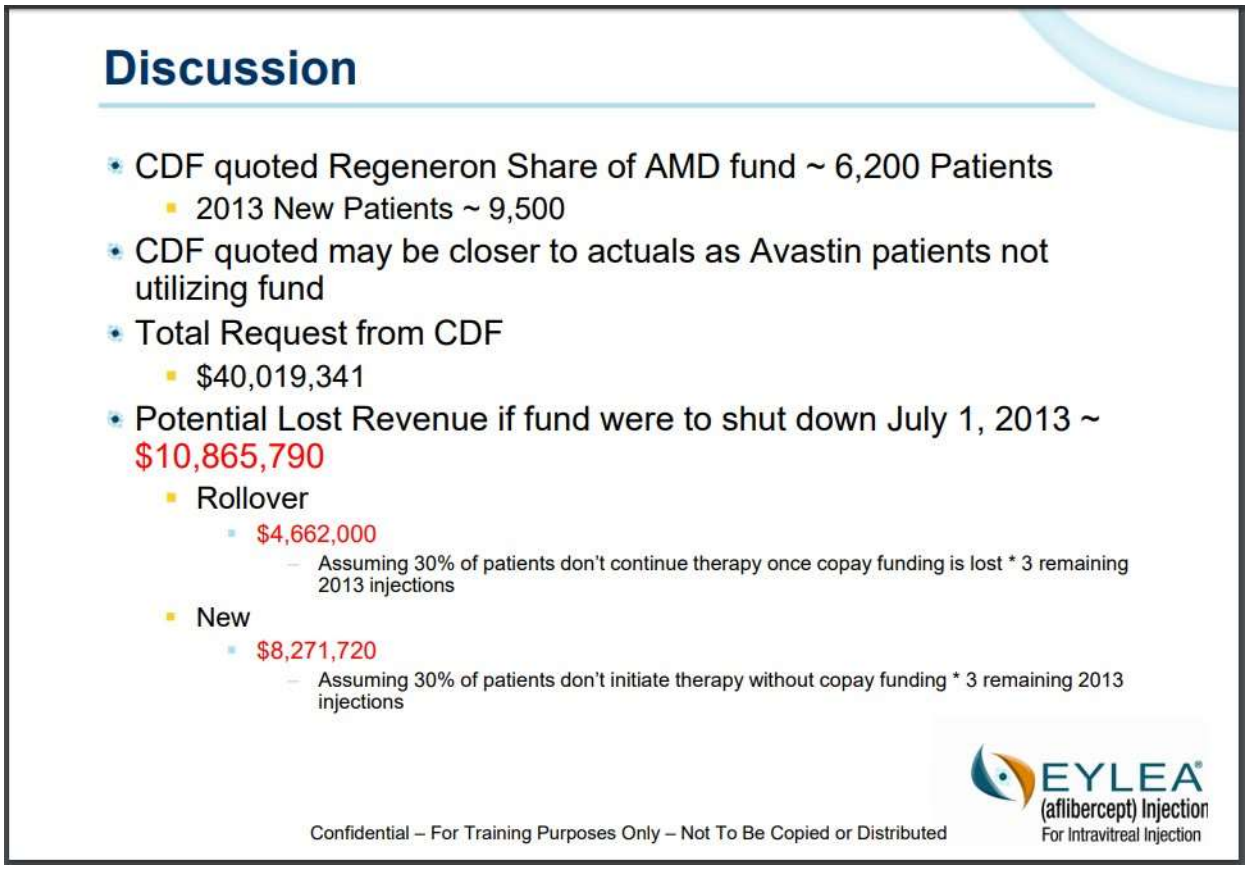
71. In the second half of 2012, Regeneron and CDF discussed the need for an increased payment for 2013 in response to Eylea's increasing market demand. Robert Krukowski, a senior

manager at Regeneron, and William Daniels, a member of his staff, communicated with Clorinda Walley, CDF's Executive Director, to determine the amount needed for 2013.

72. During those communications, CDF sent Regeneron a spreadsheet entitled "Regeneron Projections 2013," which disclosed CDF's current spending on Eylea and projected the amount CDF would need in 2013 to cover the cost-sharing obligations of Eylea patients exclusively. Ex. 2.

73. CDF's spreadsheet projected a need for more than $40 million. Regeneron's Daniels considered it unlikely that the company would approve that amount and proposed capping the payment at about $25 million: roughly $5.6 million for current Eylea patients, plus a range of $11.5 million to $19.2 million for new Eylea patients. Ex. 3 at 2, 3. With respect to the $5.6 million payment for current patients, Daniels projected that Regeneron's return on investment would be approximately $24.8 million, a more than fourfold return. *Id.*

74. In August 2012, Daniels analyzed the risks to Regeneron of an inadequate payment to CDF. According to the analysis, CDF had warned that "if every donor doesn't cover their market share [for 2013], the fund will be closed." Ex. 4 at 6. As shown in the following slide (*id*. at 10), Daniels emphasized that Regeneron would lose millions of dollars in potential sales revenue if it failed to fund CDF adequately.



75. Subsequently, Daniels circulated a revised analysis which increased the projected loss of revenue in the absence of adequate funding. Ex. 5.

76. In October 2012, Daniels and Krukowski met with Robert Terifay, a Regeneron Vice President. Terifay rejected Daniels' analysis and proposed to limit Regeneron's payment for 2013 to $2.5 million.

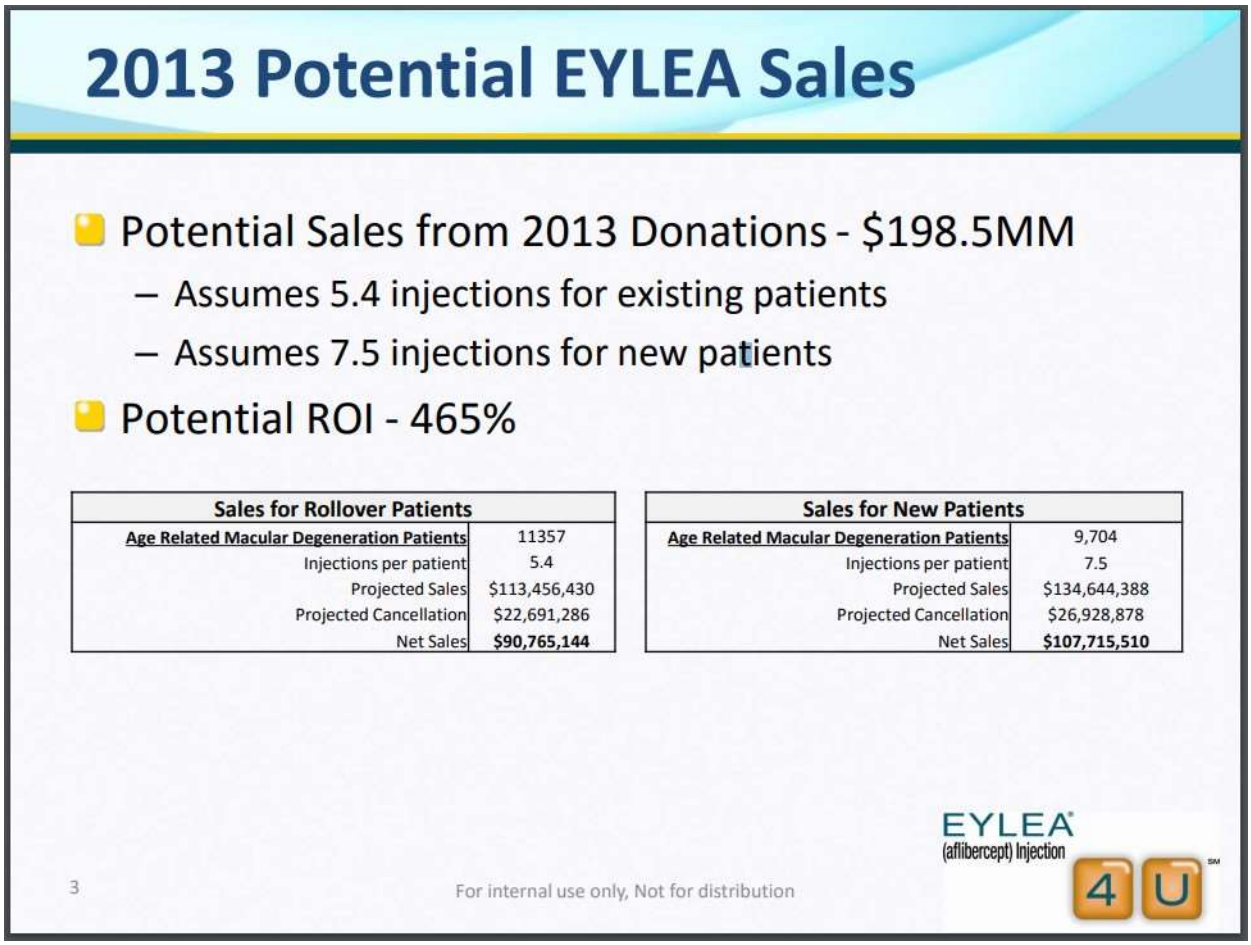
77. CDF's Walley responded in December 2012. Ex. 6. She explained that a $2.5 million donation would be insufficient and that as a result the fund would likely run out by the end of January 2013. *Id.* Walley provided another spreadsheet, titled "Regeneron Projections 2013_1219212," which reduced CDF's proposed funding from approximately $40 million to $25 million. *Id.*

78. Ultimately, in January 2013, Regeneron agreed to the roughly $25 million payment.

79. Although CDF combined the funds received from Regeneron with funds received from other manufacturers, Regeneron understood from its communications with CDF that, at least for purposes of calculating Regeneron's annual funding, the amounts to be paid by Regeneron would match the amounts CDF expected to pay for the cost-sharing obligations of Eylea patients, to the exclusion of patients using alternative drugs.

80. During the first half of 2013, Regeneron transferred $12.5 million to CDF, in accordance with Regeneron's agreement to transfer a total of $25 million for the entire year.

81. In June 2013, however, CDF sent Regeneron "updated projections" showing that CDF would need almost $35 million to pay the cost-sharing obligations of Eylea patients through the end of the year. Ex. 7 at 3. In reviewing CDF's analysis, Regeneron projected that the requested funding would yield a "potential ROI [Return on Investment]" for Regeneron of 465%, as shown in the following slide (Ex. 8 at 5):



2013 Potential EYLEA Sales

- Potential Sales from 2013 Donations - $198.5MM
  - Assumes 5.4 injections for existing patients
  - Assumes 7.5 injections for new patients
- Potential ROI - 465%

Sales for Rollover Patients	
Age Related Macular Degeneration Patients	11357
Injections per patient	5.4
Projected Sales	$113,456,430
Projected Cancellation	$22,691,286
Net Sales	**$90,765,144**

Sales for New Patients	
Age Related Macular Degeneration Patients	9,704
Injections per patient	7.5
Projected Sales	$134,644,388
Projected Cancellation	$26,928,878
Net Sales	**$107,715,510**

EYLEA (aflibercept) Injection 4U

3

For internal use only, Not for distribution

82. In July 2013, Regeneron agreed to CDF's request. For the full year, Regeneron transferred to CDF a total of $35 million.

83. For 2014, CDF projected that it would need approximately $39 million to cover the cost-sharing obligations of Eylea patients exclusively. Regeneron agreed to that amount (which included a roll-over of unused funds from 2013).

84. Because Regeneron coordinated its payments to CDF with CDF's payments to Eylea patients, CDF functioned as a direct conduit for payments by Regeneron to patients for their use of Eylea.

85. During this period, Regeneron saw clear confirmation that such payments were necessary to forestall a loss of sales due to price competition from Avastin. In early 2014, a

Regeneron sales associate reported within the company that a major physicians' group ("LIVR," or Long Island Vitreo Retinal Consultants) had been told that CDF lacked funding for Eylea and as result was switching patients to Avastin. Ex. 9. This confirmed that Eylea, costing $1,850 per dose, could not compete effectively with Avastin, costing $55 per dose, unless Regeneron paid the cost-sharing obligations of Eylea patients.

86. After 2014, Regeneron became more cautious about documenting its communications with CDF, but their coordination of payments continued for years thereafter. On information and belief, Regeneron and CDF did so by, among other things, (a) calculating the amounts needed to cover Eylea patients' cost-sharing obligations while excluding the cost-sharing obligations of patients who used competing drugs; (b) taking steps to ensure that Regeneron's funds were directed to Eylea patients rather than patients who used competing drugs; and (c) confirming on a regular basis that the revenue and return on investment resulting from Regeneron's payments would exceed the amount of those payments.

87. CDF profited from the illegal scheme by retaining a portion of Regeneron's funding as "administrative fees."

88. Regeneron's illegal scheme directly and proximately damaged MMO by causing MMO to make payments for Eylea that it would not otherwise have made.

F. Regeneron's Active Concealment of the Scheme

89. Regeneron executives received repeated warnings from subordinates that the company's relationship with CDF violated the law. For example, Regeneron's Cynthia Sherman testified in the DOJ Action that, as early as August 2011, she warned company executives that Regeneron could not legally obtain CDF's "actual utilization data" or a "breakdown" of how much CDF spent on Eylea patients and could not legally "designate [Regeneron's] donations specifically" for Eylea. Sherman testified that the executives rejected her warnings. DOJ FAC ¶ 72.

90. Similarly, in October 2012, another Regeneron employee, Robert Davis, warned company executives against obtaining Eylea-specific data from CDF. And in December of that year, Regeneron's William Daniels circulated a copy of the 2005 OIG Bulletin, quoted above, which prohibited "solicit[ing] or receiv[ing] data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products." *Id.* ¶ 74.

91. In addition, Regeneron executives confirmed their recognition that the company's relationship with CDF was illegal by concealing and misrepresenting the nature of that relationship in communications with Regeneron's internal auditors.

92. For example, in February 2013, company auditors were told that Regeneron's funding of CDF was simply "a charitable donation," and that Regeneron was not entitled to receive "information of any sort" regarding CDF's "disposition of funds." These statements were made by a Regeneron executive in an email after editing out the fact that Regeneron actually received the type of information in question. Ex. 10 at 2.

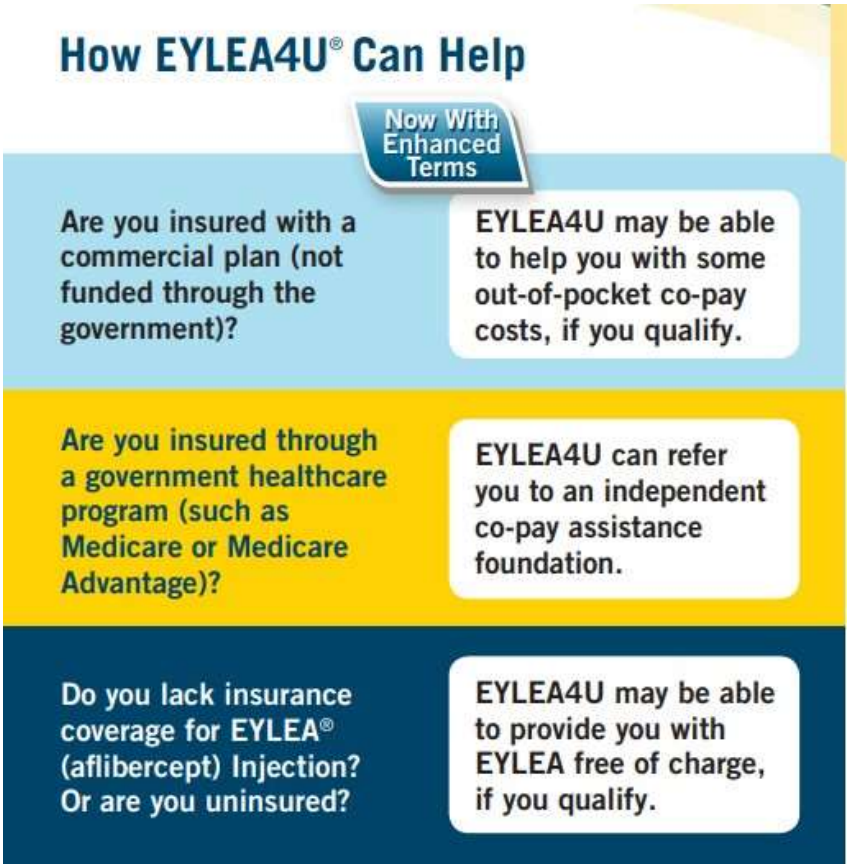
93. In November 2013, Regeneron executives again misled company auditors by falsely telling them that Regeneron received only aggregate reports from CDF, without Eylea-specific data. To support this deception, one of the executives requested and obtained from CDF an aggregate report, which he then sent to the auditors to suggest falsely that CDF's regular reports to Regeneron were transmitted in this non-specific format. Exs. 11, 12.

94. Regeneron executives concealed these facts from company auditors because they understood that public disclosure of the facts would cause MMO and other healthcare plans to refuse to pay claims for Eylea prescriptions. Regeneron's concealment had the purpose and effect of deceiving MMO and other healthcare plans, which consequently paid claims that they would not otherwise have paid.

G. Regeneron's EYLEA4U Program

95. As noted above, Regeneron enlisted the Lash Group to help run the EYLEA4U program. The Lash Group is a pharmaceutical industry consulting firm. It is a subsidiary of AmerisourceBergen Corp. and thus is a corporate affiliate of Xcenda, which helped Regeneron develop its arrangement with CDF. On information and belief, the Lash Group created, implemented, and operated the EYLEA4U program as alleged below, under Regeneron's supervision, direction, and control, and was paid to do so by Regeneron.

96. The Lash Group advertised and promoted the EYLEA4U program to physicians with promises that it would help "meet the reimbursement and copay assistance needs of you and your patients." Ex. 13 at 3. The following is a typical EYLEA4U advertisement (Ex. 14 at 4):



97. EYLEA4U materials distributed by the Lash Group to physicians and patients

misrepresented CDF as "an independent co-pay assistance foundation." *Id.*

98. EYLEA4U materials falsely claimed on websites and in promotional materials that "Regeneron does not influence or control the operations of patient assistance programs through independent charitable foundations." Ex. 15 at 3.

99. The EYLEA4U program publicized these and similar falsehoods to patients, physicians, and the public at large to conceal Regeneron's illegal kickback scheme with CDF.

100. Physicians submitted insurance information to the EYLEA4U program on behalf of their Eylea patients. The EYLEA4U program referred most or all of them to CDF. The EYLEA4U program thus served as a pipeline to connect Eylea patients with CDF, and worked directly with CDF to ensure that Eylea patients would receive the funds provided by Regeneron.

101. The EYLEA4U program served not only to connect Eylea patients with CDF but also to inform physicians of the availability of funding to cover their Eylea patients' cost-sharing obligations. The program sought to assure physicians that if they prescribed Eylea, EYLEA4U would facilitate coverage of their patients' out-of-pocket costs. In doing so, the program gave physicians an incentive to prescribe Eylea instead of the much-cheaper Avastin.

102. CDF also communicated directly with physicians to provide assurances concerning the availability of coverage for patients if the physicians prescribed Eylea. The EYLEA4U program facilitated such direct communications by disseminating CDF's contact information.

103. Through advertisements, promotional materials, and direct communications, the EYLEA4U program provided assurances and funding that made Eylea financially more attractive than Avastin for patients and physicians. In choosing among competing drugs, physicians and patients prefer drugs that are less costly for the patient. The EYLEA4U program rendered Eylea less costly for the patient than Avastin, and in fact rendered Eylea cost-free.

104. In addition to providing financial incentives to use Eylea, the EYLEA4U program

facilitated the flow of money from MMO and other healthcare plans for the payment of claims for Eylea prescriptions, even though the claims were tainted by Regeneron's illegal scheme.

105. The EYLEA4U program provided comprehensive "reimbursement support" for physicians who prescribed Eylea. The program told physicians that, before beginning a patient's treatment, they should submit an "EYLEA4U Enrollment to begin the process of helping your patients receive assistance." Once enrolled, the program could access the patient's healthcare benefits and provide the physician with a "thorough BI [benefits investigation]" that "summarizes your patient's coverage, PA [prior authorization] requirements, cost responsibility, and any additional coverage information." Ex. 16 at 3. As part of this process, EYLEA4U representatives contacted MMO and other healthcare plans to verify patients' benefits relating to Eylea.

106. EYLEA4U also helped physicians prepare patients' healthcare claims and then assisted in shepherding the claims through to payment by MMO and other healthcare plans. The program told physicians:

> EYLEA4U is available to support your office with claims and appeals assistance. If you have questions or need information to prepare a claim, we're here to help. We can also check the status of an existing claim with the patient's insurer. Simply contact one of our knowledgeable Reimbursement Specialists.
>
> If you received an underpaid or denied claim for EYLEA, we can provide you with information on how to resolve the issue. We can also research and explain the insurer's appeal process in detail.

Id.

107. Through EYLEA4U's contacts with healthcare plans, Regeneron was aware of the cost-sharing requirements and other contractual provisions under which MMO and other healthcare plans covered patients' healthcare costs. Consequently, Regeneron's interference with those provisions through its illegal kickback scheme was knowing and intentional.

108. The EYLEA4U program used the interstate wires and mail in a pervasive,

nationwide campaign to distribute, publicize, and communicate the false statements and engage in the contacts alleged above.

H. Regeneron's Dependence on Eylea Sales and Third-Party Reimbursements

109. The EYLEA4U program helped Regeneron increase Eylea's market share while maintaining the drug's exorbitant market price.

110. Since 2012, Eylea has generated $31.5 billion in sales for Regeneron, and has accounted for a majority of Regeneron's total sales revenue on an annual basis.

111. In its Form 10-K filing for fiscal year 2013, Regeneron warned investors that "EYLEA net sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product." For this reason, difficulties with continued commercialization of Eylea would cause material harm to the company. Regeneron Pharmaceuticals, Inc., Annual Report (Form 10-K), at 20 (Feb. 13, 2014), available at https://investor.regeneron.com/sec-filings/sec-filing/10-k/0001532176-14-000008.

112. In the same filing, Regeneron also emphasized Eylea's dependence on reimbursement by third-party payers like MMO: "Since EYLEA is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize EYLEA will be materially adversely impacted." *Id.* at 22.

113. The filing also noted the threat posed by equally effective, lower-cost competition in the wet AMD treatment market. In particular, physicians were using Avastin "with success," and Avastin's "relatively low cost" posed "a significant competitive challenge" to Eylea. *Id.*

114. In 2015, Regeneron again warned investors about its dependence on Eylea and the risk it faced from any limitations on reimbursements for Eylea. In its section on Eylea risks, the company focused investors' attention on the cost-cutting efforts undertaken by private healthcare

plans like MMO: "[T]hird-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs." Regeneron Pharmaceuticals, Inc., Annual Report (Form 10-K), at 26 (Feb. 11, 2016), available at https://investor.regeneron.com/sec-filings/sec-filing/10-k/0001532176-16-000045.

115. The continued commercial success of Eylea, despite its far higher cost relative to Avastin, confirms the nature and ongoing effect of Regeneron's illegal scheme. In 2020, Eylea generated $4.9 billion in sales for Regeneron, or roughly 58% of Regeneron's total sales revenue for that year. Regeneron Pharmaceuticals, Inc., Annual Report (Form 10-K), at 5 (Feb. 8, 2021), available at https://investor.regeneron.com/sec-filings/sec-filing/10-k/0001804220-21-000008. In 2019, Eylea accounted for roughly 71% of the company's sales revenue. *Id.* at 42. To date, Eylea remains Regeneron's best-selling product. *Id.* at 5.

116. And Regeneron has continued to emphasize its dependence on reimbursements for Eylea from healthcare plans such as MMO and other third-party payers:

> ***Sales of EYLEA are dependent on the availability and extent of reimbursement from third-party payers, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.***
>
> ***Our sales in the United States of EYLEA are dependent, in large part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid.*** Sales of EYLEA in other countries are dependent, in large part, on similar programs in those countries. In the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. ***For example, in September 2011 the Office of Inspector General (OIG) of the Department of Health and Human Services issued a report entitled "Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration" in which the OIG details possible savings to the Medicare program by using off-***

> ***label, repackaged Avastin rather than Lucentis for the treatment of wet AMD.*** Economic pressure on state budgets may also have a similar impact. A reduction in the availability or extent of reimbursement from U.S. government programs could have a material adverse effect on the sales of EYLEA. In addition, other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. ***Since EYLEA is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize EYLEA will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed.***

Regeneron Pharmaceuticals, Inc., Annual Report (Form 10-K), at 26 (Feb. 11, 2016), available at https://investor.regeneron.com/sec-filings/sec-filing/10-k/0001532176-16-000045 (first emphasis in original, other emphases added).

I. MMO's and the Classes' Damages

117. To date, MMO has paid more than $39.9 million to cover patients' costs with respect to Eylea.

118. Before Regeneron and its co-conspirators interfered with MMO's formulary system, MMO's members were heavily incentivized to choose Avastin over Eylea for treatment of wet AMD. All of the more than $39.9 million of MMO's Eylea payments were therefore caused directly by Regeneron's scheme.

119. Regeneron concealed and misrepresented its illegal arrangement with CDF until it was disclosed by the DOJ Action in 2020. Without further disclosures, MMO is unable to determine the full scope of the damages to itself and the class caused by Regeneron's misconduct. Given that, since 2012, Eylea has generated $31.5 billion in sales for Regeneron, it is likely that damages to the Class are measured in the billions.

VI. CLASS ACTION ALLEGATIONS

120. MMO brings this action on its own behalf and on behalf of all others similarly situated, as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages pursuant to the federal Racketeer Influenced and Corrupt Organizations ("RICO") Act, state consumer protection and/or unfair and deceptive trade practices laws, insurance fraud, state common law governing fraudulent concealment, tortious interference with contractual relationships, and unjust enrichment, as representative of a Class defined as follows:

> All third-party payers in the United States, its territories, and commonwealths who purchased, paid and/or provided reimbursement for some or all of the purchase price of Eylea (aflibercept), other than for resale, at any time during the period from January 1, 2012 through and until the Present (the "Class Period").

121. Excluded from the Class are:

a. Regeneron and its counsel, officers, directors, management, employees, subsidiaries, and affiliates;

b. Natural persons; and

c. Pharmacy benefit managers

122. Members of the Class are so numerous and widely geographically dispersed throughout the United States and its territories that joinder is impracticable. Plaintiff believes that there are hundreds of thousands of members of the Class, in an amount to be determined in discovery and at trial. Further, the identities of Class members will be readily ascertainable through business records kept in regular order.

123. Plaintiff's claims are typical of the claims of members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Regeneron.

124. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, the Class.

125. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

126. Questions of law and fact common to members of the class predominate over questions, if any, that may affect only individual Class members, because Regeneron has acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Regeneron's wrongful conduct. Questions of law and fact common to the Class include, but are not limited to:

a. Whether Regeneron gained an unfair advantage by distorting the cost of Eylea in the view of patients and their prescribers, while increasing the costs borne by Medicare and private healthcare plans including MMO and Class members;

b. Whether Regeneron's scheme covertly funneled illegal kickbacks to patients through CDF;

c. Whether Regeneron violated the federal Anti-Kickback statute;

d. Whether Regeneron misrepresented and concealed material facts concerning its illegal arrangement with CDF;

e. Whether Regeneron violated the Racketeer Influenced and Corrupt Organizations Act;

f. Whether Regeneron violated state consumer protection laws and/or unfair and deceptive trade practices laws (see Count III);

g. Whether Regeneron intentionally and tortiously interfered with the cost-sharing provisions in MMO's and Class members' contracts thus

causing MMO and Class members to breach their agreements by failing to pay the cost-sharing obligations set forth in their healthcare plans; and

h. Whether Regeneron was unjustly enriched.

127. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

128. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.[2]

Count I: Violation of Civil RICO, 18 U.S.C. § 1962(c)

129. MMO incorporates by reference and realleges the foregoing paragraphs as if they were expressly restated here.

130. Regeneron is a "person" within the meaning of 18 U.S.C. § 1961(3).

131. Regeneron conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

132. Regeneron, CDF, and the Lash Group entered into an association-in-fact enterprise (the "Enterprise") within the meaning of 18 U.S.C. § 1961(4). The Enterprise was an ongoing organization that functioned as a continuing unit. Regeneron, CDF, and the Lash Group are each "persons" distinct from the Enterprise. Each of them had the common purpose of conducting, and

[2] MMO reserves the right to amend the class definition and/or add subclasses.

actually did conduct, a pattern of racketeering activity through the Enterprise.

133. Regeneron established the Enterprise to increase its sales of Eylea and increase Eylea's market share while maintaining Eylea's price despite competition from lower-cost alternatives. Regeneron enlisted CDF as a means of eliminating the cost-sharing obligations of Eylea patients through illegal payments, thereby inflating demand for Eylea at the expense of MMO and other healthcare plans. Regeneron enlisted the Lash Group to advertise and promote the funneling of CDF's payments to patients, and to monitor and facilitate payments by MMO and other healthcare plans in response to the illegally inflated demand for Eylea. The Enterprise fraudulently used interstate wires and mail to conceal and misrepresent the illegal aspects of the scheme, thereby causing MMO and other healthcare plans to pay tainted claims that they would not have paid absent the fraud.

134. Each participant in the Enterprise played a distinct and essential role in conducting a pattern of racketeering activity through the Enterprise. Regeneron marketed and sold Eylea and unlawfully coordinated its payments to CDF so that Regeneron's funds were used solely for the benefit of patients using Eylea as opposed to alternative drugs. CDF provided Regeneron with the information needed to coordinate its funding and served as the conduit for transmitting those funds to Eylea patients exclusively. The Lash Group ensured through the EYLEA4U program that physicians and patients were aware of and able to utilize those funds and facilitated payments from MMO and other healthcare plans to cover Eylea's costs.

135. Each participant in the Enterprise profited as a result. Regeneron reaped billions of dollars in Eylea sales induced and facilitated by the Enterprise's illegal scheme; CDF retained a portion of Regeneron's funding as "administrative fees"; and the Lash Group received payments from Regeneron for operating the EYLEA4U program. Each participant in the Enterprise benefited from the Enterprise's success.

136. The participants in the Enterprise acted in unison and coordinated their efforts to achieve a common purpose, and their coordinated efforts were essential to the Enterprise's success.

137. Regeneron operated and controlled the Enterprise as a conduit for improperly funneling payments to cover patients' out-of-pocket expenses. Regeneron did so under the guise of the EYLEA4U program with the assistance and cooperation of CDF and the Lash Group.

138. Regeneron conducted and participated in the affairs of the Enterprise through a pattern of racketeering activity that included predicate acts indictable under 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), and 1952 (use of interstate facilities to conduct unlawful activity). As alleged above, Regeneron committed at least two such acts during a ten-year period.

139. Regeneron's predicate acts included at least the following: use of the interstate wires and mail to (a) distribute or facilitate the distribution of false advertising and promotional materials in support of Regeneron's illegal kickback program; (b) transmit or facilitate transmission of physicians' (unwittingly) false certifications and claims to MMO and other healthcare plans; (c) distribute or facilitate the distribution of false advertising and promotional claims denying that Regeneron exercised any influence or control over CDF's payments to Eylea patients; and (d) transmit other communications that fraudulently concealed and misrepresented the illegal nature of the Enterprise.

140. Regeneron and the Enterprise used the interstate wires and mail in at least the following respects: (a) coordinating Regeneron's illegal payments to CDF through written and oral communications between Regeneron and CDF executives; (b) transmitting illegal payments from Regeneron to CDF, and from CDF to patients or their physicians; (c) coordinating with the Lash Group to use the EYLEA4U program to facilitate payments by MMO and other healthcare plans for Eylea claims tainted by illegal kickbacks; (d) disseminating false and misleading information to physicians, patients, and the general public (including MMO) concerning the availability of

purportedly "charitable" funding and the nature of Regeneron's relationship with CDF; (e) causing physicians to transmit (unwittingly) false certifications that claims for Eylea's costs complied with federal and state law; and (f) facilitating payments by MMO and other healthcare plans with respect to claims tainted and rendered non-payable by Regeneron's illegal kickback scheme.

141. These acts constitute a sustained pattern of racketeering activity. The racketeering activity began in 2012 and continued until at least 2020. To this day, Regeneron's entire financial condition depends crucially on sales of Eylea, its top-selling product. Consequently, Regeneron retains an overwhelming interest in perpetuating its illegal scheme and poses a threat of continued racketeering activity.

142. On information and belief, the relationships between and among Regeneron, CDF, and the Lash Group extended beyond the unlawful predicate acts alleged above.

143. Each participant in the Enterprise knew that its activities in furtherance of the Enterprise and Regeneron's kickback scheme violated federal and state law.

144. The Enterprise engaged in and affected interstate commerce because, among other things, Regeneron and CDF illegally funded Eylea prescriptions for thousands of patients throughout the United States; and Regeneron, CDF, and the Lash Group controlled, operated, or participated in the EYLEA4U program, which promoted the scheme to physicians and patients throughout the United States and facilitated the processing and payment of patients' claims by MMO and other healthcare plans throughout the United States.

145. The alleged racketeering activity had the purpose and effect of causing MMO and other healthcare plans to pay claims for Eylea that they would not have paid if they had known the nature of that activity and its effect on identifiable claims. MMO suffered injury to its business or property as a direct and proximate result.

146. By virtue of the foregoing, MMO and the Class are entitled to three times the

damages they have incurred, in an amount to be determined at trial, and other relief permitted by law.

Count II: Conspiracy to Violate Civil RICO, 18 U.S.C. § 1962(d)

147. MMO incorporates by reference and realleges the foregoing paragraphs as if they were expressly restated here.

148. 18 U.S.C. § 1962(d) provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

149. Regeneron has violated 18 U.S.C. § 1962(d) by conspiring with CDF and the Lash Group to violate 18 U.S.C. § 1962(c). The objective of their conspiracy has been to conduct, or participate directly or indirectly in the conduct of, the affairs of the Enterprise through a pattern of racketeering activity, as alleged above.

150. Regeneron and its co-conspirators have engaged in numerous predicate acts that constitute overt acts in furtherance of the alleged conspiracy, as alleged above.

151. The nature of those acts establishes that Regeneron, CDF, and the Lash Group not only conspired to violate 18 U.S.C. § 1962(c) and thus violated 18 U.S.C. § 1962(d), but also that they were aware that their course of conduct constituted a pattern of racketeering activity.

152. The alleged conspiracy, and the overt, predicate acts committed in furtherance of the conspiracy, had the purpose and effect of causing MMO and other healthcare plans to pay claims for Eylea that they would not have paid if they had been aware of the conspiracy and its effect on identifiable claims. MMO suffered injury to its business or property as a direct and proximate result.

153. By virtue of the foregoing, MMO and the Class are entitled to three times the damages they have incurred, in an amount to be determined at trial, and other relief permitted by law.

Count III: Unfair and Deceptive Practices Under State Laws
(For MMO's and the Class's Eylea Purchases)

154. MMO incorporates by reference and realleges the foregoing paragraphs as if they were expressly restated here.

155. Regeneron's conduct was directed to and impacted MMO and members of the Class through the members MMO serves.

156. By engaging in the conduct described herein, Regeneron deceived MMO and Class members into making payments on claims for Eylea that it otherwise would not have paid.

157. In addition to affecting MMO, Regeneron's conduct also affected other similarly situated third-party payers, as evidenced by the case filed by the United States against Regeneron.

158. Skyrocketing drug prices present a significant harm to third-party payers, a burden on the United States healthcare system, and a substantial contributing factor to the overall rise in healthcare costs in the United States. Regeneron's scheme subverted the primary restraint on the price of Eylea, allowing Regeneron to inflate its price well beyond what the market would otherwise bear.

159. Regeneron's deceptive conduct directly and proximately caused MMO and Class members to suffer damages in the form of payments made on claims for Eylea that were not due and that would not otherwise have been made.

160. Regeneron engaged in deceptive practices in connection with its sale of Eylea, and suppressed material facts related thereto, as described above. Regeneron's actions deceived MMO and Class members, directly and proximately damaging MMO and Class members by causing them to pay claims for Eylea that they would not have paid otherwise and / or to pay higher prices for Eylea than they would have paid otherwise.

161. Regeneron's nationwide fraudulent and deceptive business practices described

herein violated the state consumer fraud, consumer protection, and/or unfair and deceptive trade practices laws of the following states:[3]

a. Alaska stat. §§ 45.50.471, *et seq.*, with respect to purchases of Eylea in Alaska;

b. Ark. Code §§ 4-88.-101, *et seq.*, with respect to purchases of Eylea in Arkansas;

c. Ariz. Code §§ 44-1522, *et seq.*, with respect to purchases of Eylea in Arizona;

d. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Eylea in California;[4]

e. Colo. Rev. Stat § 6-1-105, *et seq.*, with respect to purchases of Eylea in Colorado;

f. Conn. Gen. Stat. § 6-1-105, *et seq.*, with respect to purchases of Eylea in Connecticut;

g. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases of Eylea in the District of Columbia;

h. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Eylea in Florida;

i. 815 ILCS §§ 505/1, *et seq.*, with respect to purchases of Eylea in Illinois;

j. Ind. Code §§ 24-5-0.5-1, *et seq.*, with respect to purchases of Eylea in Indiana;

k. Kan. Stat. §§ 50-623, *et seq.*, with respect to purchases of Eylea;

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a. [3] Following pre-suit notices to the defendants, MMO intends to amend this complaint to add claims under the following statutes: Ga. Stat. § 10-1-390, et seq., with respect to purchases of Eylea in Georgia;
b. 5 Me. Rev. Stat §§ 207, et seq., with respect to the purchases of Eylea in Maine;
c. Mass. Gen. Laws Ch. 93A, et seq., with respect to purchases of Eylea in Massachusetts;
d. W. Va. Code §§ 46A-6-101, et seq., with respect to purchases of Eylea in West Virginia; and
e. Miss. Code. Ann. § 75-24-1, *et seq.*, with respect to purchases of Eylea in Mississippi.

[4] MMO will provide the defendants with notice within 30 days after the date of this complaint in accordance with CAL. CIV. CODE § 1782(a).

l. Ky. Rev. Stat § 367.110, *et seq.*, with respect to purchases of Eylea in Kentucky;

m. La. Rev. Stat Ann. §51:1 401, *et seq.*, with respect to the purchases of Eylea in Louisiana;

n. Md. Com. Law Code § 13-101, *et seq.*, with respect to purchases of Eylea in Maryland;

o. Mich. Stat §§ 445.901, *et seq.*, with respect to purchases of Eylea in Michigan;

p. Minn. Stat. § 325F.69, subd. 1, with respect to purchases of Eylea in Minnesota;

q. Missouri Stat §§ 407.010, *et seq.*, with respect to purchases of Eylea in Missouri;

r. N.J. Rev. Stat § 56:8-1, *et seq.*, with respect to purchases of Eylea in New Jersey;

s. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Eylea in Nebraska;

t. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of Eylea in Nevada;

u. N.H. Rev. Stat. §§ 358~A:1, *et seq.*, with respect to purchases of Eylea in New Hampshire;

v. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of Eylea in New York;

w. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of Eylea in North Carolina;

x. Okla. Stat. tit. 15, § 751, *et seq.*, with respect to purchases of Eylea in Oklahoma;

y. Pa. Stat. Ann. § 201-1, *et seq.*, with respect to purchases of Eylea in Pennsylvania;

z. P.R. Laws Tit. 10, § 260, *et seq.*, with respect to purchases of Eylea in Puerto Rico;

aa. R.I. Gen. Laws § 6-13.1-1, *et seq.*, with respect to purchases of Eylea in

Rhode Island;

bb. S.C. Stat. Ann. § 39-5-10, *et seq.*, for purchases of Eylea in South Carolina;

cc. Tenn. Code 47-18-101, *et seq.*, with respect to purchases of Eylea in Tennessee;

dd. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of Eylea in Virginia;

ee. 12A V.I.C. § 101, *et seq.*, with respect to purchases of Eylea in the U.S. Virgin Islands;

ff. Wis. Stat. § 100.18; Wis. Stat. § 100.20, *et seq.*, with respect to purchases of Eylea in Wisconsin.

gg. Wyo. Stat. Ann. § 40-12-101, *et seq.*, with respect to purchases of Eylea in Wyoming.

162. MMO paid and/or reimbursed for claims on Eylea treatment for members in many of the foregoing states, including Arkansas, Arizona, California, Colorado, Connecticut, District of Columbia, Florida, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, New Jersey, Nebraska, Nevada, New Hampshire, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Virginia, Wisconsin, and Wyoming, due to Regeneron's fraudulent scheme in the following amounts, as of the date of this complaint.

163. Class members paid claims on Eylea treatment for members in the foregoing states due to Regeneron's fraudulent scheme in the following amounts, as of the date of this complaint.

164. MMO and Class members relied on these misrepresentations to their detriment, which were material to their decision to pay for Eylea.

165. Regeneron's conduct offends established public policy and the public interest, and is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

166. MMO and Class members are therefore entitled to actual damages or damages for each deception that occurred, punitive damages, and attorney's fees.

167. Regeneron violated the state statutes knowingly and willfully, specifically targeting MMO and other healthcare plans that covered the costs of Eylea prescriptions. Regeneron's conduct directly and proximately injured MMO. Consequently, MMO is entitled to recover the appropriate damages under each state's laws, in an amount to be determined at trial, and other acceptable relief permitted by law.

Count IV: Fraudulent Concealment and Fraud

168. MMO incorporates by reference and realleges the foregoing paragraphs as if they were expressly restated here.

169. Regeneron's fraudulent scheme specifically targeted healthcare plans such as MMO. As alleged above, Regeneron has expressly acknowledged that its entire financial condition depends heavily on healthcare plans' payments for Eylea.

170. As alleged above, Regeneron's EYLEA4U program monitored and facilitated the payment of claims by MMO and other healthcare plans. Regeneron and its agents regularly communicated with MMO as part of that process.

171. During those communications, Regeneron misrepresented and concealed material facts concerning its illegal arrangement with CDF, as alleged above. Those facts included, among others: Regeneron and CDF illegally calibrated Regeneron's funding to match the needs of Eylea patients exclusively; as a result, CDF was not acting as an independent, bona fide charity but rather as a conduit for Regeneron's illegal kickbacks to patients for choosing Eylea over alternative, less expensive drugs; and absent this illegal arrangement, healthcare plans such as MMO would have paid for a lower volume of Eylea prescriptions, at potentially lower prices.

172. MMO was unaware of Regeneron's illegal scheme until June 2020, when the DOJ

Action was filed.

173. The facts misrepresented and concealed by Regeneron were material to MMO's decision to pay for Eylea claims. If MMO had known those facts, it would have refused to pay for identifiable claims tainted by Regeneron's unlawful scheme.

174. Regeneron knew that MMO lacked such knowledge and that, as a result, MMO paid claims for Eylea that it otherwise would not have paid.

175. Regeneron further understood that physicians and other healthcare providers who submitted claims to MMO's plans on behalf of Eylea patients would certify that the claims were not tainted by illegal kickbacks. Regeneron's scheme thus caused physicians and providers to submit, unwittingly, false certifications for patients whose cost-sharing obligations were unlawfully paid for by Regeneron through CDF.

176. Regeneron knew that its relationship with CDF violated the federal Anti-Kickback statute, rendering those certifications false.

177. Regeneron further knew that MMO lacked knowledge of the falsity of those certifications, and that MMO would rely on the certifications in paying claims for Eylea.

178. MMO had no reason to suspect that Regeneron and CDF were engaged in an illegal kickback scheme. MMO reasonably believed that the relationship between Regeneron and CDF complied with legal requirements.

179. Regeneron knew and intended that MMO and other healthcare plans would rely on (a) physicians' and other providers' false certifications, and (b) Regeneron's misrepresentations and concealments of material facts concerning its relationship with CDF. MMO actually and reasonably relied on those false certifications, misrepresentations, and concealments.

180. As a result of such reliance, MMO paid claims for Eylea that should not have been paid under both its private commercial healthcare plans and its Medicare plans, and suffered

millions of dollars in damages, the amount of which is to be determined at trial.

181. By virtue of the foregoing, MMO is entitled to compensatory and punitive damages, in amounts to be determined at trial, and other relief permitted by law.

Count V: Tortious Interference with Contract

182. MMO incorporates by reference and realleges the foregoing paragraphs as if they were expressly restated here.

183. MMO's benefit plans, incluge plding its Medicare Advantage plans, require that covered patients personally bear the cost-sharing obligations provided by the plans when obtaining prescription drugs such as Eylea.

184. Regeneron knew that MMO's plans contained these cost-sharing provisions, which are standard features of healthcare plans. Regeneron deliberately sought to subvert these provisions through its illegal kickback scheme. By rendering Eylea cost-free for patients, Regeneron improperly increased the demand for Eylea and maintained the drug's exorbitant price, improperly increasing the costs MMO and other healthcare plans were required to pay for Eylea.

185. In doing so, Regeneron intentionally and tortiously interfered with the cost-sharing provisions in MMO's contracts. Regeneron's interference caused MMO members to breach their agreements with MMO by failing to pay the cost-sharing obligations set forth in their healthcare plans.

186. Regeneron's interference and procurement of those contractual breaches was wrongful and without justification, and intended to defeat the structure of MMO's managed care system and to benefit Regeneron financially at MMO's expense.

187. The contractual breaches Regeneron caused have directly and proximately caused significant damages to MMO in the form of payments made by MMO that it would not have made if MMO had known that identifiable claims were tainted by Regeneron's illegal scheme.

188. By virtue of the foregoing, MMO is entitled to compensatory and punitive damages, in amounts to be determined at trial, and other relief permitted by law.

Count VI: Unjust Enrichment

189. MMO incorporates by reference and realleges the foregoing paragraphs as if they were expressly restated here.

190. MMO has conferred direct benefits on Regeneron in the form of payments made by MMO for Eylea claims tainted by Regeneron's illegal scheme.

191. Regeneron has voluntarily and knowingly accepted and retained those benefits and has been unjustly enriched as a result, to MMO's unjust detriment.

192. By virtue of the foregoing, MMO is entitled to recover the amount of Regeneron's unjust enrichment, to be determined at trial, and other relief permitted by law.

VII. JURY DEMAND

MMO, on behalf of itself and the class, demands a jury trial of all issues triable of right by a jury.

VIII. PRAYER FOR RELIEF

Plaintiffs request that the Court enter judgment in their favor and grant the following relief:

a. Treble damages under 18 U.S.C. § 1964(c);

b. Treble or at least double damages under the applicable state laws;

c. Compensatory and punitive damages;

d. Appropriate equitable and injunctive relief;

e. Court costs and reasonable attorneys' fees;

f. Prejudgment and post-judgment interest; and

g. Any further relief the Court deems just and proper.

Dated: February 23, 2022

By: _____
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